JAN 13 2006

K053499

Section 3

HemosIL ProS

510(k) Summary (Summary of Safety and Effectiveness)

Submitted by:

Instrumentation Laboratory Company
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Contact Person:

Carol Marble, Regulatory Affairs Director
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Summary Prepared:

December 15, 2005

Name of the Device:

HemosIL ProS

Classification Name:

864.7290	Factor Deficiency Test	Class II
81GGP	Test, Qualitative and Quantitative Factor Deficiency	

Identification of Predicate Device(s):

K011424 HemosIL ProS

Description of the Modified Device:

HemosIL ProS is a functional assay for the quantitative determination of free Protein S in human citrated plasma on IL coagulation systems as an aid in the diagnosis of hereditary and acquired Protein S deficiency.

The reconstituted and onboard stability claims for HemosIL ProS on the ACL Futura (K951891) and ACL Advance (K002400) are being revised as a precautionary measure based on indications from internal QC release data on multiple product lots.

Statement of Technological Characteristics of the Device Compared to Predicate Device:

The performance of HemosIL ProS with modified stability claims for the ACL Futura and ACL Advance is not materially different from the FDA cleared device.

Summary of Performance Data:

Based on additional stability testing on the ACL Futura/ACL Advance, we are revising the onboard claim to 1 hour and the reconstituted 2-8°C claim to 12 hours to ensure the optimal integrity of the product in the field.

All other performance testing was within specification and is consistent with the currently labeled claims in the product insert for HemosIL ProS.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Carol Marble
Regulatory Affairs Director
Instrumentation Laboratory Company
113 Hartwell Avenue
Lexington, Massachusetts 02421

JAN 13 2006

Re: k053499
Trade/Device Name: HemosIL ProS
Regulation Number: 21 CFR § 864.7290
Regulation Name: Factor deficiency test
Regulatory Class: II
Product Code: GGP
Dated: December 15, 2005
Received: December 20, 2005

Dear Ms. Marble:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Robert L. Becker, Jr., MD, Ph.D
Director
Division of Immunology and Hematology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K053499

Device Name: HemosIL ProS

Indications for Use:

HemosIL ProS is a functional assay for the quantitative determination of free Protein S in human citrated plasma on IL coagulation systems as an aid in the diagnosis of hereditary and acquired Protein S deficiency.

This *in vitro* diagnostic test determines the functional activity of free Protein S by measuring the degree of prolongation of a prothrombin time in the presence of the tissue factor, phospholipids, calcium ions and activated Protein C. The Protein S activity is proportional to the prolongation of the clotting time of a Protein S deficient plasma to which the diluted sample was added.

Prescription Use √ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K053499